

REMARKS

Claims 1-5, 8-19, 21, 27-49, 51-53, 57-62, 87, 88, 90-120, 133 and 134 are currently pending in the above-identified application. Claims 1, 28, 48, 90, and 120 have been amended. Support for these amendments is found throughout the specification including, for example, at Figure 2 and paragraphs 0057, 0060, and 0192. As such, no new matter is added by these amendments.

It is submitted that the amendments do not require a new search or consideration because the amendments merely clarify the claimed subject matter and do not change the subject matter under consideration. The amendments do not add more claims than were finally rejected and, it is submitted, place the claims in condition for allowance, or in better condition for appeal. As such, it is respectfully requested that the amendments be entered.

Rejections under 35 U.S.C. §112

Claims 1-5, 8-19, 21, 27-49, 51-53, 57-62, 87, 88, 90-120, 133 and 134 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that Applicants had possession of the claimed invention at the time the application was filed. It is further alleged that the specification lacks enabling support for the language "at the outset of treatment" as recited in the rejected claims.

Applicants respectfully disagree that the originally filed application does not disclose or enable the language of generating, at the outset of treatment, a plurality of sets of appliances, as recited in the rejected claims and cited by the Examiner. As is known by the Examiner, there is no *in haec verba* requirement for satisfaction of the requirements under 35 U.S.C. §112, first paragraph. See, e.g., MPEP § 2163(I)(B). In order to advance prosecution of the present application, however, Applicants have amended independent claims 1 and 48 to recite subject matter that is more clearly supported in the originally filed specification, and the claims no longer recite the term "at the outset of treatment".

As amended, independent claims 1 and 48 recite "wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth." Applicants submit that the amendments are clearly supported throughout the originally filed specification, which is replete with description of a plurality of appliances being generated prior to any of the appliances of the plurality being used or worn by the patient so as to reposition the patient's teeth. The Examiner's attention is directed, for example, to Figure 2 of the originally filed application, where it is noted that use of the appliances specifically follows the "generate" step. The amendments are also clearly supported, for example, as at paragraphs 0057, 0060, and 0192 of the specification as originally filed.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-5, 8-19, 21, 27-49, 51-53, 57-62, 87, 88, 90-120, 133 and 134 are rejected under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §102

Claims 1-5, 8-19, 21, 27-49, 51-53, 57-62, 87, 88, 90-120, 133 and 134 are rejected under 35 U.S.C. §102(e) as being anticipated by Chishti et al. (U.S. Patent No. 5,975,893, herein after referred to as "Chishti").

Applicants gratefully acknowledge the February 1, 2006 telephone conference between the Examiner and Applicants' representative, during which the copendency of the present application and U.S. Patent No. 5,975,893 was clarified. Pursuant to the Examiner's suggestion and in order to overcome the rejection, Applicants are re-presenting below Applicants remarks previously presented in Applicants' response mailed 12/6/2005, which sets forth that the present application shares copendency with U.S. Patent No. 5,975,893 and is disqualified as prior art under 35 U.S.C. §102(e).

As set forth previously (see, e.g., Applicants's response mailed 12/6/05), Applicants direct the Examiner's attention to paragraph [0001] of the present application (reproduced below) as filed on November 20, 2003, as well as to the Application Data Sheet filed therewith, both of which clearly state the priority claim of the present application.

[0001] This application is a continuation of U.S. Application No. 09/686,190 (Attorney Docket No. 018563-004810 - AT-00105.1), filed October 10, 2000, which was a continuation of U.S. Application No. 09/169,276 (Attorney Docket No. 18563-004800 - AT-00105), filed October 8, 1998, (now abandoned), which is a continuation-in-part of PCT Application No. US98/12681 (Attorney Docket No. 18563-000120PC - AT-00003PC), filed on June 19, 1998, which claimed priority from U.S. Patent Application No. 08/947,080 (Attorney Docket No. 18563-000110 - AT-00002), filed on October 8, 1997, (now Patent No. 5,975,893), which claims priority from U.S. Provisional Application No. 60/050,342 (Attorney Docket No. 18563-000100 - AT-0001), filed on June 20, 1997, the full disclosures of which are incorporated in this application by reference.

Applicants note that the USPTO's PAIR system does not show a priority claim for the present application from U.S. Patent Application No. 08/947,080, now Patent No. 5,975,893. This application (now issued patent) was included in the priority claim as filed, however. Thus, the present application does have copendency with U.S. Patent No. 5,975,893, and Applicants therefore request withdrawal of the rejection under 35 U.S.C. § 102(e). Applicants also request that the priority claim shown on PAIR be corrected to include the 5,975,893 priority claim.

Rejections under 35 U.S.C. §103

Claims 1-5, 8, 9, 13, 21, 27-30, 32-49, 51, 52, 57, 59-62, 87, 88, 90-115, 117-120 and 133 are rejected under 35 U.S.C. §103(a) as being unpatentable over Martz (U.S. Patent No. 4,793,803, herein after referred to as "Martz") in view of Andreiko et al. (U.S. Patent No. 5,454,717, herein after referred to as "Andreiko").

Applicants respectfully disagree that it would have been *prima facie* obvious to combine Martz with Andreiko, or that any reasonable combination of the references would produce the claimed invention. See, e.g., MPEP §§2141-2143. In particular, Applicants submit that the Examiner has failed to establish 1) the requisite motivation or suggestion to combine the cited references of Martz and Andreiko; or 2) that, even if combined, the cited references would teach each and every element of the claims.

First, Applicants submit that the Examiner has failed to identify any suggestion or motivation, either in the cited references, or in the knowledge generally available to those of

ordinary skill, to combine and modify the cited references so as to produce the claimed invention. In particular, Applicants respectfully submit that the Examiners allegation that it would have been obvious to one of ordinary skill to modify Martz to include using computer models instead of real models to generate the appliances in order to make use of alternate ways of modeling tooth positions (see Final Office Action, page 4, lines 5-8) wholly lacks support in the cited references or elsewhere.

As previously made of record, Martz teaches one-at-a-time production of a set (one upper one lower appliance) of insertable/removable appliances using a manually manipulated wax set up. In contrast to Martz, Andreiko does not even deal with removable appliances, but teaches a system for making and affixing brackets and archwires, similar to those used in traditional orthodontic treatments. While Andreiko teaches using computer images and anatomical shape data, the teachings are directed to producing a single affixed appliance configured in accordance with teeth in the desired finished position, such that the brackets/archwires can be affixed to locations on the patient's teeth based on a desired finished position rather than the pre-treatment maloccluded positions.

Applicants have reviewed the cited references in detail but are unable to find any motivation or suggestion to modify the teachings of Andreiko as to produce a insertable/removable appliance as taught by Martz, instead of the conventional, affixed bracket/archwire appliance that is the focus of the Andreiko reference. Moreover, not only is the requisite motivation for the combination absent from the cited references, but no teachings have been identified in the cited references as to how such a modification would even be accomplished.

Second, Applicants submit that even if, for arguments sake only, one were to combine Martz and Andreiko, the cited references, alone or in combination, would fail to teach each and every element of the claimed invention. In particular, it is submitted that at least the features of "wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth", as recited in

independent claims 1 and 48, are not taught or suggested by Martz or Andreiko either individually or in combination, thereby precluding *prima facie* obviousness.

While the Examiner acknowledges that neither of the cited references teach generating a plurality of appliances (e.g., more than one appliance) at a single stage of treatment (e.g., at the outset of treatment), it is alleged that it would have been obvious to one of ordinary skill to modify the teachings of Martz to prepare and give the patient multiple appliances at the outset in order to not require the patient to return to the practitioner (see Final Office Action, page 4, lines 8-11). Thus, the Examiner appears to rely not on any specific teachings in the art, but on the Examiner's own assessment of what would be common sense or obvious modifications of the cited references. However, Applicants respectfully disagree and submit that the Examiner's position is not supported by any actual objective evidence in the record (other than impermissible hindsight using Applicants' own disclosure) and, therefore, lacks the requisite substantial evidence support for *prima facie* obviousness. See, e.g., MPEP § 2144.03.

Martz, at best, teaches following up an initial treatment period (i.e., fabrication and use of an appliance) with either modifications to the existing appliance, or repetition of previously cited patient examination and appliance fabrication steps. Nothing in Martz teaches or suggests generating more than one appliance (i.e., a plurality of successive appliances) prior to the patient wearing any appliance of the plurality. Furthermore, nothing is in the record, other than Applicants' own disclosure, that would teach or suggest modifying Martz in order to generate a plurality of appliances prior to the patient wearing any appliance of the plurality. Martz, in fact, teaches just the opposite of the modification proposed by the Examiner in teaching that "as time goes on, movement of the teeth may be accomplished through multiple stages of the appliance by utilizing more than one wax setup." (Martz at col. 4, lines 12-15; emphasis added).

As is well known by the Examiner, the Office bears the initial burden of factually establishing and supporting any assertion of *prima facie* obviousness, including both motivation to combine cited references (see above) and evidence that the cited references teach each and every element of the claims. In the present case, the Examiner has not pointed to any actual evidence in Martz or Andreiko, or knowledge of those skilled in the art, that would provide 1)

the requisite motivation or suggestion to combine the cited references; or 2) that, even if combined, the cited references would teach each and every element of the claims. It is well established, however, that an assessment made on alleged basic knowledge and common sense that is not based on any actual and objective evidence in the record lacks the substantial evidence required to support a case of *prima facie* obviousness. See, e.g., *In re Zurko* 258 F.3d 1379, 1385; 59 USPQ2d 1693, 1697 (Fed.Cir.2001); MPEP § 2144.03.

Therefore, it is respectfully submitted that the rejections of the claims should be withdrawn for the reasons set forth above or, if the rejections are not withdrawn, that the Examiner provide some objective indicia, separate from the Applicants' own disclosure (e.g., impermissible hindsight reconstruction) to support the Examiners' position that one of ordinary skill would have had any motivation to combine the teachings of Martz with those of Andreiko as to produce the claimed invention, and that, even if combined, the cited references would teach each and every element of the currently claimed invention.

While Applicants do not agree with the instant rejection and submit that the Examiner has failed to establish *prima facie* obviousness for at least the reasons set forth above, in order to further expedite prosecution of the instant application, Applicants have attached hereto a Declaration under 37 C.F.R. § 1.132 by Dr. Eric Kuo ("Kuo Declaration"). The Kuo Declaration, along with supporting Exhibits A-J, and as further summarized herein below, demonstrates that the subject matter of the current claims has found considerable success in the market, thereby providing objective evidence against the position that the currently claimed methods would have been obvious in view of any prior art available at the time of the invention.

The Align Technology, Inc. (assignee of record of the current application) Invisalign® product has been very successful in the orthodontic market. Traditionally, patients had to wear braces for comprehensive orthodontic treatment. A number of patients, particularly adults, avoided orthodontic treatment because of aesthetic concerns associated with fixed orthodontic braces. Additionally, traditional orthodontic treatment was often painful as well as inconvenient (restrictions to diet and certain sports activities, plus the occasional emergency visit to fix a

broken wire or loose band/bracket. Brushing and flossing of teeth was also more difficult. As a result, there was a need in the market for a more aesthetic orthodontic appliance that required little to no adjustment and made eating, brushing and flossing easier. Orthodontists were looking for an appliance that could reduce their chair time with patients (and hence increase their practice capacity and productivity), draw more new patients into the practice, reduce the pain and inconveniences associated with fixed orthodontic treatment, and better promote the health of the teeth and gums during treatment through ease of brushing and flossing. Align's Invisalign® system meets each of these needs; as a result, it has found considerable success in the market. (Kuo Declaration at paragraph 5).

The commercial success of the Align's Invisalign® system is directly related to the features that are described in Align's U.S. Patent Application no. 10/718,779 and the corresponding pending claims, as well as in other pending applications and issued patents owned by Align (Kuo Declaration at paragraph 6). Since the introduction of Align's Invisalign® system, it has created a significant revenue stream from 1999 through 2005, and the revenue has increased dramatically over the relevant years (Kuo Declaration at paragraph 7; Exhibit A). Additionally, the number of new patients using Align's product has increased dramatically since the introduction of the product (Kuo Declaration at paragraph 8; Exhibit B). Along with the dramatic increase in revenue and number of new patients, the cumulative number of individual aligners shipped by Align has increased dramatically from 1999 to 2005 (Kuo Declaration at paragraph 9; Exhibit C). Additionally, the number of doctors starting cases using Align's product has increased from 2003 to 2005 (Kuo Declaration at paragraph 10; Exhibit D). The steady increase of the number of doctors trained in the Invisalign system from 2002 to 2005 also shows the success of Align's Invisalign® since its introduction (Kuo Declaration at paragraph 11; Exhibit E). The number includes doctors who did not previously perform orthodontic treatments before being trained in the Invisalign® system. *Id.* Align's Invisalign® system has also received a number of awards (Kuo Declaration at paragraph 12; Exhibits F–H). The success of Align's Invisalign® system is also reflected in praises and acceptance by professionals and academia. (Kuo Declaration at paragraph 13; Exhibit I). Moreover, the Invisalign System has

been primarily due to the innovative product and method of manufacture as covered by Align's U.S. Patent Application no. 10/718,779 and other pending applications and issued patents of Align and not primarily due to expenditure of advertising (Kuo Declaration at paragraph 14; Exhibit J).

Accordingly, for the reasons set forth above, withdrawal of the rejections of claims 1-5, 8, 9, 13, 21, 27-30, 32-49, 51, 52, 57, 59-62, 87, 88, 90-115, 117-120 and 133 under 35 U.S.C. §103(a) is respectfully requested.

Claims 10-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over Martz in view of Andreiko as applied to claim 1 above, and further in view of Lemchen et al. (U.S. Patent No. 5,845,717, herein after referred to as "Lemchen").

The combination of Martz and Andreiko is traversed for the reasons set forth above. Lemchen fails to provide the teachings that are missing from Martz and Andreiko. In particular, at least the features of "wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth", as recited in independent claim 1, are not taught or suggested by the cited references either individually or in combination, and one of ordinary skill would have no motivation to combine the cited references in the first place.

Furthermore, Applicants submit that Lemchen does not teach segmenting dentition, as alleged by the Examiner. In fact, the term "segmenting" does not appear in Lemchen and it is unclear how the provision of Lemchen cited by the Examiner (i.e., col. 12, lines 26-29) relates to applying a set of predefined rules to segment the initial data set into 3D models of individual dentition components of the patient's mouth, as required by claims 10-12.

Furthermore, the Kuo Declaration, along with supporting Exhibits A-J, and as further described above, additionally demonstrates the non-obviousness of the subject matter of the current claims.

Accordingly, Applicants respectfully request that the rejection of claims 10-12 under 35 U.S.C. §103(a) be withdrawn.

Claims 14-19 and 53 are rejected under 35 U.S.C. §103(a) as being unpatentable over Martz in view of Andreiko as applied to claim 1 above, and further in view of Doyle (U.S. Patent No. 5,879,158, herein after referred to as "Doyle").

The combination of Martz and Andreiko is traversed for the reasons set forth above. Doyle fails to provide the teachings that are missing from Martz and Andreiko. At least the features of "wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth", as recited in independent claims 1 and 48, are not taught or suggested by the cited references either individually or in combination, and one of ordinary skill would have no motivation to combine the cited references in the first place.

Furthermore, the Kuo Declaration, along with supporting Exhibits A-J, and as further described above, additionally demonstrates the non-obviousness of the subject matter of the current claims.

Accordingly, Applicants respectfully request that the rejection of claims 14-19 and 53 under 35 U.S.C. §103(a) be withdrawn.

Claims 31, 58, 116 and 134 are rejected under 35 U.S.C. §103(a) as being unpatentable over Martz in view of Andreiko as applied to claim 1 above, and further in view of Robertson (U.S. Patent No. 5,340,309, herein after referred to as "Robertson").

The combination of Martz and Andreiko is traversed for the reasons set forth above. Robertson fails to provide the teachings that are missing from Martz and Andreiko. At least the features of "wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth", as recited in independent claims 1 and 48, are not taught or suggested by the cited references either individually or in combination, and one of ordinary skill would have no motivation to combine the cited references in the first place.

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Furthermore, the Kuo Declaration, along with supporting Exhibits A-J, and as further described above, additionally demonstrates the non-obviousness of the subject matter of the current claims.

Accordingly, Applicants respectfully request that the rejection of claims 31, 58, 116 and 134 under 35 U.S.C. §103(a) be withdrawn.


CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Date: 5/25/06

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